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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/496,893	02/02/2000	Stephen J. Brown	7553.00030 / 00-0220	6810

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EXAMINER	
SMITH, CAROLYN L	

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/496,893	BROWN, STEPHEN J.	
	Examiner	Art Unit	
	Carolyn Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *83-98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *83-98* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date. _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

In view of the appeal brief filed on 4/10/09, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below.

/Marjorie Moran/

Supervisory Patent Examiner, Art Unit 1631

Applicant's arguments, filed 4/10/09, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 83-98 are herein under examination.

Claim Rejections – 35 U.S.C. 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of the skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

LACK OF ENABLEMENT

Claims 83-98 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed invention.

It is well known that the Human Genome Project has revealed that the number of human genes is in the range of 30,000. Even this number is controversial. Applicant's invention is directed to the defining groups based on responses to queries, comparing genotype information between groups, and then generating a report that represents a subset of genotype information in order to select disease-influencing genes or identify individuals having a disease-influencing gene. It is also well known that a multitude of polymorphisms exists in human genes caused by environmental factors such as chemicals or cosmic rays. These complications result in an unpredictable length and difficulty in a research project that simply clusters individuals via queries regarding the behavior or other characteristics to then isolate or focus on one or more disease-influencing gene(s), even if guided by disease risk factors. It is known that some genetic sequences are correlated with particular diseased individuals, but that each of these sequences was elucidated by lengthy research projects where the findings of the gene sequence was difficult and unpredictable. Thus, the clustering of individuals, which has been known for many diseases already has not predictably resulted in gene identification, nor will the practice of the instant invention predictably result in the selection or identification of disease-influencing gene(s) or the identification of individuals having a disease-influencing gene. The publication of Doberstein et al. (previously mailed with a previous office action) was cited regarding paragraphs 0003-0008 to support the numerous difficulties involved in relating gene sequences to other factors even utilizing modern bioinformatics tools. It is also noted one skilled in the art would not scientifically conclude that simply comparing genotype information (instant claim 83) or comparing genotype information based on groups formed using query responses (instant claims 90 and 94) results in the identification or selection of a disease-influencing gene or identification

of individuals having a disease-influencing gene. Furthermore, selecting genes needed to be processed for medical research further documents the undue experimentation recited in these claims. For these reasons, the instant claims are rejected due to a lack of enablement.

Applicant discusses requirements of a lack of enablement rejection. Applicant summarizes instant claim 83 and clarifies the "after defining", "comparing", and "generating" steps of instant claim 83. Applicant lists passages in the specification that mention these latter steps. It is noted that in order to make and use the invention, the body of the claim should be able to reach the intended result in the preamble. The end step of instant claim 83 generates a report that represents a subset of genotype information. From this last step, one skilled in the art cannot get to the intended result of selecting one or more disease-influencing genes.

Applicant reiterates arguments of instant claim 83 (and dependent claims 84-89) for instant claims 90-98. These arguments are deemed unpersuasive for the reasons given above.

Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 83-93 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

The preamble of claim 83 recites selecting one or more disease-influencing genes whereas the body of the claim recites selecting individuals, but not genes. In addition, the body of the claim recites generating a report representing a subset of genotype information, which is not necessarily one or more disease-influencing genes. Therefore, it is not clear if the preamble is intended to limit the method and what relationship is intended between the preamble and method steps. Claims 84-89 are also rejected due to their dependency from claim 83.

The preamble of claim 90 recites selecting one or more disease-influencing genes whereas the body of the claim does not recite selecting genes, but rather identifying one or more individuals having a disease-influencing gene. Therefore, it is not clear if the preamble is intended to limit the system and what relationship is intended between the preamble and body of the claim. Claims 91-93 are also rejected due to their dependency from claim 90.

Applicant argues that the mere fact that the body of the claim recites elements which do not appear in the claim's preamble does not render the claim indefinite. Applicant argues that if the body of a claim sets forth all limitations of the claimed invention, and the preamble merely states the purpose or intended use rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction.

It is still unclear if Applicant intends the preamble to limit the method and system. It is noted the bodies of claims 83 and 90 do not arrive at the intended result of the preambles of these claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 83-86 and 88-98 are rejected under 35 U.S.C. 102(e) as being anticipated by Lapointe et al. (US 6,678,669).

Lapointe et al. disclose a method and system for identifying new markers for disease to design new tests and improve the sensitivity and specificity of tests as well as medical diagnostic tests (abstract; col. 1, last paragraph; col. 3, last two paragraphs; col. 5, last paragraph; col. 20, third paragraph; claim 38) which represents a method and system for selecting one or more disease-influencing genes needed to be processed for medical research (as stated in the preambles of instant claims 83, 90) as well as identifying individuals having a disease-influencing gene (as stated in the preamble of instant claim 94). Lapointe et al. disclose collecting observation by examining and querying a group of test patients in whom the medical

condition is known (claim 38; col. 6, fourth paragraph) which represents selecting individuals having a risk factor for a disease, as stated in instant claim 83. Lapointe et al. disclose the method and system are computer-based with a consensus of networks and several processors involving input interface screen and inputting patient information (claims 1, 3; col. 2, first paragraph; col. 6, fourth paragraph; col. 9, second paragraph; col. 10, lines 60-62; col. 84, second to third paragraph; Figure 11), as well as a computer connectable with a monitoring device that monitor pulse rate or blood pressure (col. 11, seventh paragraph; col. 12, seventh paragraph; col. 15, seventh paragraph) with the system adapting to the particular environment (col. 6, last paragraph) which represents providing a communications apparatus (as stated in instant claim 83, 90), a communication network (as stated in instant claims 90, 94), a communication apparatus connectable with a monitoring device (as stated in instant claim 88, 94) involving blood pressure and pulse rate (as stated in instant claims 89, 94, 96). Lapointe et al. disclose sending queries to each individual, for example "Do you smoke?" supplied in a computer-readable form to a system operating on a computer (instant claims 3, 38; col. 15, seventh paragraph) and using a script program (col. 89-239; Figures 11 and 13) which represents sending queries to each individual through an apparatus (as stated in instant claim 83, 94) and script-based queries (as stated in instant claims 84, 90, 91, 95) and a script program (as stated in instant claims 85, 91, 95). Lapointe et al. disclose answers to questions, collecting input data storing patient data and further train systems to develop systems that are adapted to a particular genetic population, inputting additional data (claim 38; col. 6, fourth and last paragraphs; col. 9, second paragraph) which represents receiving and storing responses of each individual, as stated in instant claims 83, 90. Lapointe et al. disclose categorizing observations and defining similar

groups, categorizing responses from patient historical questionnaires, and categorizing women into different classes (claims 38, 52; Figure 4; col. 30, lines 45-46; col. 14, fifth paragraph; col. 15, fourth and fifth paragraphs) which represents defining a plurality of groups. Lapointe et al. disclose before, during or after collecting observations from a group of test patients, performing biochemical tests on at least one test patient and categorizing them into a set of candidate variables and providing biochemical test results for all or a subset of patients for whom the patient data are known with biochemical tests including bioassays and collecting genetic history of a patient and using genetic algorithms (claims 60, 116; col. 22, second paragraph; col. 25, fourth paragraph) using a genetic algorithm and NeuroGenetic Optimizer and Knowledge discovery in data (KDD) which identifies relationships among variables as well as identifying variables and sets thereof ranking variables and finding correlations (col. 13, last paragraph; col. 7, third paragraph to col. 8, first paragraph; col. 18, lines 17-67; col. 20, third and fifth paragraphs; col. 22, second paragraph), which represents receiving and comparing genotype information, as stated in instant claims 83, 90, 92, 94, 97. Lapointe et al. disclose developing systems for a particular genetic population, identifying subsets of relevant variables and outputting information (col. 6, fourth to sixth paragraphs; col. 8, second paragraph; col. 13, third paragraph; col. 27, third paragraph; claim 37) which represents generating a report, as stated in instant claim 83. Lapointe et al. disclose categorizing individuals via identifying the disease state or condition of a patient as well as adapting systems for a particular genetic population (claim 38, col. 6, second and last paragraphs) and diabetes (col. 9, third paragraph) which represents categorizing individuals into groups by disease progression including diabetes, as stated in instant claims 86, 92, 93, 97, 98.

Thus, Lapointe et al. anticipate instant claims 83-86 and 88-98.

Other prior art

Although not being used as prior art, the following reference is being made of record: Herren et al. (US 6,108, 635) disclose a method and integrated disease information system with an interface involving querying, receiving user input of biological parameters, projecting disease progression outcomes taking risk factors into account for various groups, and analyzing for each group of patient types based on standard categories of factors.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. If you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you

would like assistance from a USPTO Customer Service Representative or access to the automated information system, please call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on (571) 272-0720.

July 18, 2009

/Carolyn Smith/
Primary Examiner
AU 1631